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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,575	09/24/1999	THOMAS J. BACHINSKI	293/008-CONT	1763

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NEW YORK, NY 10020

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/406,575	Applicant(s) BACHINSKI ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27-75,87 and 89-147 is/are pending in the application.
- 4a) Of the above claim(s) 25,27-43 and 95-143 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-75, 87, 89-94, and 144-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/26/04</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 25, 27-43, and 95-143 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse by original presentation.

Specification

The amendment filed July 26, 2004 adds new matter to the specification that is not permitted; see 37 CFR 1.121 (f). In particular, in the replacement paragraph of pages 24 and 25, the new language is considered new matter because it is not clear that twisting or the resilient segments inherently occurs to move the clips of this embodiment of Figures 25 and 26. For this reason, the Examiner asserts that this change adds new matter to the specification. Applicants must delete the new matter in response to this Office action or show that this subject matter has original support.

It is noted that the description of Figure 30 on page 30, lines 15-30 suggests a twisting of some elements occurs. However, since this is to a different embodiment, it is not seen how it teaches that the same thing occurs in the different embodiment of Figures 25 and 26.

Claim Objections

Claims 46-52 and 65-75 are objected to as having the same scope. In particular, each of claims 46-52 have a scope that is identical to each other. In addition, claims 69-72 have the same scope. Finally, claims 73-75 have identical scopes. If these claims are allowed, Applicant will be required to cancel all but one of the duplicate claims of each set.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 87 and 89-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, it is not clear where the language "configuration change is effected by expanding the ring" has original support. Rather, the configuration change appears to be effected by a balloon expanding the tissue engaging portions (see Figure 26a) or by allowing tissue-engaging portion to resiliently spring out to the expanded state. There is no suggestion that the configuration change is effected by expanding the ring as now claimed.

It is noted also, that the Applicants failed to comply with the last paragraph of page 5 of the previous Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 144-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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With regard to claims 144-147, the terminology of the claim is inconsistent with the specification such that the claim language is considered unclear lacking clear antecedent basis; see MPEP 2173.03 which is incorporated herein by reference. In particular, the amended specification on pages 24 to 25 does not give antecedent basis to the claim language because the clip segments of Figure 25 do not engage two blood vessels as claimed. For this reason, it is not clear how this language has antecedent support from the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 92-94 and 144-147 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaster (US 5,234,447). Kaster anticipates the claim language where the cylindrical portion(s) as claimed is met by the connecting unit (46), the twisting joints are the joints in the engaging members (44) adjacent connecting unit (46) that bend to allow the engaging members (44) to twist about the connecting unit; see Figures 10 and 19 and column 4, line 16 to column 7, line 14.

Claims 44-75, 87, 89-94, and 144-147 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldsteen et al (US 5,976,178) or Goldsteen et al (US 6,206,912). Both Goldsteen patents have identical disclosures and anticipate the claimed invention where the cylindrical portion as claimed is ring (430a) of Goldsteen, the spikes or clips as claimed are barbs (436") of Goldsteen, and the twisting joints or segments as claimed are at the bases of barbs (436"); see Figures 34, 35, and 38 as well as column 16, line 60 to column 17, line 36 and column 18, line 37 to column 19, line 25.

With regard to claim 44 specifically, the expansion of ring (430a) inherently results in spike engagement because the same structure as disclosed in the present application is present in the Goldsteen patents as well.

Regarding claims 87 and 89-91, the Goldsteen patents disclose connectors with two configurations that operate in the same manner as that disclosed by the present application. However, these claims are only anticipated by Goldsteen if the configuration change is effected by expanding the cylindrical portion. Therefore, these

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claims are considered anticipated to the extent that the configuration change is effected by expanding the cylindrical portion thereof.

Response to Arguments

Applicant's arguments filed July 13, 2004 have been fully considered but they are not persuasive.

In response to the declaration under 37 CFR 1.132 alleging that the claimed invention was invented only by the inventors in the present application, the Examiner asserts that the declaration is insufficient because it does not unequivocally show that the claimed invention was only invented by the present inventors. In particular, the inventive entities of both patents as compared to the present invention are different because the patents have an additional inventor Rudy Mazzocchi. The fact that the present application incorporates the disclosure of the patents is not considered persuasive in clearly showing that the inventorship is correct. Furthermore, the declaration is made by only one of the current inventors and not by all the inventors as required; see MPEP 716.10, which is incorporated herein by reference.

With regard to the arguments that Kaster does not have tissue penetrating tips, the Examiner asserts that since the ends of Kaster go through tissue, whether there is a hole previously formed in the tissue or not, that the claim language is fully met. The claims do not require the tips be capable of forming a hole in a particular type of tissue as Applicants apparently read into the claims.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilo
Primary Examiner
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